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Name of Patentees: Krall et al.
Patent No.: 6,037,366 Date Patent Issued: March 14, 2000
Title of Invention: COMPOSITION FOR CREATING VASCULAR OCCULSIONS

BOX REISSUE
Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

This Preliminary Amendment is being filed prior to examination of the above-identified application. Applicants respectfully request the entry of the following amendments to the claims.

In the claims

Please add new claims 6 to 16. Please amend claims 1, 3, and 5 as follows:

1. (amended) A composition for creating therapeutic vascular occlusions in an animal comprising a mixture of:

(a) Part 1 comprised of 2-hexyl cyanoacrylate, hydroquinone, p-methoxyphenol and phosphoric acid; and

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(b) Part 2 comprising gold metal powder, [ethyl myristate] a fatty acid ester and a [sterilized] stabilized polymer of 2-hexyl cyanoacrylate [in weak aqueous bicarbonate solution].

3. (amended) The composition of claim 2 wherein Part 2 comprises about 65 percent by weight gold, about 30 percent by weight ethyl myristate and the remainder said sterilized polymer of 2-hexyl cyanoacrylate [in weak aqueous bicarbonate solution].

5. (amended) A method for creating therapeutic vascular occlusions in an animal needing therapeutic vascular occlusion comprising the steps of:

(a) Mixing together Part 1 comprised of 2-hexyl cyanoacrylate, hydroquinone, p-methoxyphenol and phosphoric acid with Part 2 comprising gold metal powder, [ethyl myristate] a fatty acid ester, and a [sterilized] stabilized polymer of 2-hexyl cyanoacrylate [in weak aqueous bicarbonate solution]; and

(b) [injecting] administering the mixture into a vascular site needing occlusion [with the gold metal powder suspended in the mixture].

Please add the following new claims:

--6. A composition for creating therapeutic vascular occlusions in an animal comprising a mixture of:

(a) Part 1 comprised of a cyanoacrylate liquid monomer, hydroquinone, p-methoxyphenol and phosphoric acid; and

(b) Part 2 comprising a radiopaque metal powder, a fatty acid ester and a stabilized polymer of cyanoacrylate.

7. The composition of claim 6, wherein the cyanoacrylate is 2-hexyl cyanoacrylate.

8. The composition of claim 6, wherein the radiopaque metal powder is gold, tantalum, or platinum.

9. The composition of claim 6, wherein the vascular occlusion is created in an arteriovenous malformation (AVM).

10. The composition of claim 6, wherein the fatty acid ester is ethyl myristate.

11. A method for creating therapeutic vascular occlusions in an animal needing therapeutic vascular occlusion comprising the steps of:

(a) mixing together Part 1 comprised of cyanoacrylate, hydroquinone, p-methoxyphenol and phosphoric acid with Part 2 comprising a radiopaque metal powder, a fatty acid ester and a stabilized polymer of cyanoacrylate; and

(b) administering the mixture into a vascular site needing occlusion.

12. The method of claim 11, wherein the cyanoacrylate is 2-hexyl cyanoacrylate.

13. The method of claim 11, wherein the radiopaque metal powder is gold, tantalum, or platinum.

14. The method of claim 11, wherein the fatty acid ester is ethyl myristate.

15. The method of claim 11, wherein the vascular occlusion is created in an arteriovenous malformation (AVM).

16. The method of claim 11, wherein the administering is by a catheter or by percutaneous methods.--

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Remarks

By the present communication claims 1, 3 and 5 have been amended and new claims 6 to 16 have been introduced. No new matter is introduced by the new claims submitted herewith as the new claim language is fully supported throughout the specification and original claims.

In independent claims 1 and 5, the ethyl myristate claimed as an element of the composition has been amended to more broadly claim as "a fatty acid ester." Ethyl myristate is a type of fatty acid ester. The specification disloses that, "any of the large chain fatty acid esters will work to replace ethyl myristate" (col. 2, lines 1-3. *See also* col. 3, lines 47-50). The broader class of fatty acid esters should have been claimed in the original claims to this invention.

In independent claims 1 and 5, the polymer of 2-hexylcyanoacrylate has been amended to require that the polymer is "stabilized," rather than "sterilized," In the specification, the polymer of part 2 of the composition is shown to be stabilized and sterilized simultaneously. (col. 2, lines 24-26.) The resulting polymer is stable. The polymer in this stable state was available to be claimed in the claims of the original application, but was not. Therefore the language describing the polymer of 2-hexyl cyanoacrylate should read "stabilized," rather than "sterilized."

Also in independent claims 1 and 5, the part 2 of the claim requires "a weak aqueous bicarbonate solution." As can be seen in column 2, lines 10-14, the weak aqueous bicarbonate solution is used in the preparation of the polymer that is part of the claimed composition. However, the weak aqueous bicarbonate solution is not itself an element in the claimed composition. Therefore the claim has been changed to remove the language "in a weak aqueous bicarbonate solution" from claims 1 and 5.

The language of dependent claim 3 has been amended to reflect the changes in claims 1 and 2, from which it depends.

Additionally, in claim 5, part (b), the mixture does not necessarily have to be injected. Many methods of delivery are available. The specification of the present invention simply discusses "the delivered product," (col. 2, lines 51-62) but not specific methods of delivery. Claim 5 has been broadened to recite "administering."

In claim 5, the language "with the gold metal powder suspended in the mixture" has been deleted. While this is a characteristic disclosed in the specification, it is not necessary to the invention. Therefore that language has been removed from part (b) of claim 5.

New claims 6 to 16 have been added. These claims provide further protection for the invention, but do not add any new matter. Independent claims 6 and 11 are directed to the previously unclaimed broad inventive concept of the invention, as set forth in the specification. Support for claim 6 can be found in the specification at, for example, col. 1, lines 59-61, col. 1,

lines 66 to col. 2, line 4, col. 2, lines 24-26, and col. 3, lines 42-45. Support for claim 11 can be found in the specification at, for example, col. 1, lines 51-52, col. 1, line 59 to col. 2, line 3, and col. 2, lines 34-38. Dependent claims 7 to 10 and 12 to 16 are directed to additionally disclosed, but previously unclaimed, features of the broad inventive concept. These claims are supported by the specification. Support for claim 7 and 12 can be found in the specification at, for ex., col. 1, lines 64-65 and col. 3, lines 19-24. Support for claim 8 and 13 can be found in the specification at, for ex., col. 3, lines 42-45. Support for claims 9 and 15 can be found in the specification at, for example, col. 2, lines 34-36. Support for 10 and 14 can be found in the specification at, for example, col. 2, lines 1-3. Support for claim 16 can be found in the specification at, for example, col. 1, lines 50-51.

During the prosecution of the Application, the full scope of the invention as it relates to the elements of the claimed composition was not appreciated. The claims as submitted in this reissue application more broadly and more fully claim the disclosed invention.

The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Respectfully submitted,

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